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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,310	08/25/2000	Paul B. Fisher	62943/JPW/JML	6406

7590 01/11/2006

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/648,310	FISHER ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,56,58,64,70,72,74 and 80* is/are rejected.

7)☒ Claim(s) *55,57,59-63,65-69,71,73,75-79 and 81-85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 10/17//2005 is acknowledged.

Claims 54-85 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 54, 56, 58, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number AA891725 (a copy provided on 1/30/2003, 08-JAN-1999).

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 2 (claim 54), vector containing said nucleic acid (claim 56), a host cell containing said nucleic acid (claim 58), host cell containing said vector (claim 64).

Applicant argues that GenBank accession number AA891725 does not disclose a protein encoding Progression Suppressed Gene-I3 protein (SEQ ID NO: 2); It merely described an undefined EST (Expressed Sequence Tag) sequence derived from rat kidney mRNA with partial homology to the nucleic acid encoding SEQ ID NO:2; This sequence when reversed and complemented contained the complete open reading frame for Progression Suppressed Gene-I3 protein; However even if persons skilled in the art conceptually translated the sequence disclosed in AA891725, they would find it encoded several possible protein sequences or open reading frames; In addition, since AA891725 is in a reverse orientation, even less guidance is provided as to its capacity

to encode a protein set forth in SEQ ID NO:2; T7 and T3 promoters and clone RKIAG02 pertain to bacteriophage promoters and bacterial host cells respectively; Such expression systems may be effective in expressing a RNA sequence from a DNA placed between the two promoters but would not express the protein set forth in SEQ ID NO:2.

These arguments have been fully considered but found unpersuasive because the instantly claimed isolated nucleic acid structure and the nucleic acid structure disclosed in AA891725 are identical. The previously provided sequence alignment demonstrates that the insert cDNA disclosed in AA891725 ("undefined EST" as applicant describes in traversing the art rejection) encodes instant SEQ ID NO: 2. As for the new limitation "permit expression of a rat Progression Suppressed Gene-13 protein" in claim 54, the previously provided Bonaldo et al (1996, Genome Research, vol. 6, pages 791-806) at page 803, left column, under the heading "In Vitro Synthesis of library RNA" teach that RNA synthesized with T3 RNA polymerase is in the antimessage orientation and it is complementary to single-stranded circles in vivo. This teaching along with the insert information disclosed in AA891725 indicate that the cDNA is under T3 promoter shown at Fig. 6.

As for the argument that T3 promoter does not express protein from DNA, the Office cites Technical Bulletin for TnT® coupled Reticlulocyte Lysate Systems downloaded from world wide web at promega.com on 1/3/2006. The Technical Bulletin under the heading "I. Description" and also under Fig. 1 and 4 teaches that a protein is translated if the nucleic acid coding the protein is under T3 promoter.

Claims 70, 72, 74, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number N39717 (22-JAN-1996).

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 4 (claim 70), vector containing said nucleic acid (claim 72), a host cell containing said nucleic acid (claim 74), host cell containing said vector (claim 64), and host cell containing vector of claim 72 (claim 80).

Applicant argues that as in the response to rejection of claim 54 and its dependent claims, the cited reference does not anticipate claims directed to the human Progression Elevated Gene-l3 protein (SEQ ID NO:4) or related nucleic acid, vectors and host cells; The claims are not anticipated because the standard of strict identity required for a rejection based on anticipation is not met; The undefined EST sequence N39717 even when linked to T7 and T3 promoters and present in a bacterial clone does not disclose a nucleic acid encoding Progression Suppressed Gene-l3 protein or host cell expressing such protein.

These arguments have been fully considered but found unpersuasive.

GenBank accession number N39717 discloses an isolated nucleic acid comprising a nucleic acid encoding instant SEQ ID NO:4. Note the previously provided Exhibit A (a sequence alignment of the nucleic acid encoding the instant SEQ ID NO:4 against the nucleic acid disclosed in GenBank accession number N39717) showing the nucleic acid of GenBank accession number N39717 inherently encodes the entire instant SEQ ID NO:4, i.e. 100 % identical. The EST insert encoding the instant SEQ ID NO:4 is in pT7T3Pac, which is designed to put a cDNA insert operatively to a promoter.

Note Bonaldo et al (cited above). As for host cell, the vector containing the cDNA insert is in ampicillin resistant DH10B.

As for the argument that T3 promoter does not express protein from DNA, the Office cites Technical Bulletin for TnT® coupled Reticlulocyte Lysate Systems downloaded from world wide web at promega.com on 1/3/2006. The Technical Bulletin under the heading "I. Description" and also under Fig. 1 and 4 teach that a protein is translated if the nucleic acid coding the protein is under T3 promoter.

Conclusion

The objected claims are objected because they depend on the rejected base claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Misook Yu 1-9-06

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642